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(54) **DEVICE FOR TREATING TISSUES, FOR EXAMPLE SKIN.**

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CH - A - 470 878
DE - A - 2 809 828
DK - B - 131 270
DK - B - 131 805
FR - A - 1 255 501
FR - A - 1 336 118
GB - A - 641 061
US - A - 2 280 915
US - A - 3 026 874
US - A - 3 367 332
US - A - 3 753 439
US - A - 3 797 494
US - A - 3 996 934

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Description

The present invention relates to a device for treatment of a tissue area in an abnormal condition comprising a porous material intended for abutment against the tissue and a fluid-impervious shell or layer which covers the material at least to an extent, said device having at least one connection for fluid supply and at least one connection for fluid removal.

Devices for the treatment of tissues, such as skin, are previously known from US—A—2 280 915 and DE—A—2 809 828, both of which relate to shells adapted to be clamped against the tissue and having a fluid inlet and a fluid outlet through which fluid is supplied and removed from the space defined by the shell. Shells of this type are of limited usefulness, and the fluid flow in the said space may adversely affect e.g. and open wound. Furthermore, it is known from US—A—3 996 934 to administer drugs via the skin by means of a bandage held thereagainst. An administration bandage of this type can be used only in very special cases for the treatment of wounds or the like.

A device termed "drain" is known from US—A—3 753 439. This device comprises a cylindrical shell with centrally arranged catheters. The cylindrical shape makes the device unfit for practical use because tissue cavities seldom are cylindrical, but have irregular walls. If this device were positioned in a cavity, the major portion of the cavity, upon continuous supply of fluid by suction, would be filled with fluid, in any case to the most proximal suction opening, before an efficient drainage could be established. Due to the central localisation of the two catheters and the construction with lateral openings on a level with one another, and also due to the fact that the cavity is filled with fluid, a readily controllable treatment flow contacting the entire damaged area, cannot be established.

The object of the present invention is to realize a device which makes possible an easily handleable and, for the patient, more comfortable device for treating ulcers and skin injuries or the like, which entails rapid healing under conditions which are safe with regard to the risk of infection. This object is achieved by means of a device which is characterised in that the porous material consists or at least one layer of open-pore soft cellular material that can be readily conformed to said tissue area, that the fluid-impervious shell only is disposed, at least to an extent, on one side of the cellular material and that the connections for fluid supply and removal are connected to the shell in a spaced apart relationship in order to establish a treatment fluid flow coming into contact with the tissue area through the cellular material from the supply connection to the removal connection for influencing the tissue by sorptive processes, preferential passage of substances with the treatment fluid flow, by chemical processes and/or by tempering.

The invention will be described in greater detail below with reference to accompanying drawings which schematically illustrate embodiments of the invention.

Fig. 1 is top plan view of a simple embodiment of the invention and

Fig. 2 is a section taken along the line II—II in Fig. 1.

Figs. 3, 4 and 5 show the device in operation and illustrate how the device works on treatment of a tissue.

The device according to the invention consists of a cellular material layer 11 with a communicating cavity system and a covering shell or layer 10 of fluid-impervious material. The shell 10 has at least one fluid supply connection 12 and at least one fluid removal connection 13. Thus, fluid can be supplied by the intermediary of the connection 12, as illustrated by means of arrows 18, and be caused to flow through the cellular material 11 and be led off via the connection 13, as shown by means of arrows 19. In order to facilitate fluid passage through the cellular material, the fluid can be supplied under pressure and/or be removed by suction. In the supply conduit, there is coupled a regular member 15 which accommodates a valve means and means for cooling and/or heating the fluid which is supplied to the cell material. A sensor 16 which is arranged to sense fluid saturation in the cellular material, is placed therein and connected to the valve means of the regulator member 15 by a conduit 17. Fluid-impervious members 20 are disposed at the transitions of the connections 12, 13 into the cellular material in order to guide the flow.

The cellular material 11 constitutes a cavity system in the form of cells with open pores or communicating capillary systems, or consists of particles with interposed communicating gaps. The material can be synthetic, e.g. consist of polyurethane or similar plastics material, or may consist of regenerated cellulosic fibres with a binder of, for example, polyester polyamide on fabric. The material may consist of sponge or rubber or contain another type of elastic component. The structure can also be realized by overlaid particles of small size of plastics/glass/ceramics or the like. Organic compounds may be basic materials, for example cellulosic fibres of e.g. dextran polymer particles cross-linked with epichlorohydrin (Sephadex-Debrisan®, possibly with glycerin or the like as binder). If particles are used as material, it may be practical to utilize continuous layers with open pores adjacent the skin or tissue layer which is to be treated.

The material can be inert with respect to chemical substances, biological particles and bacteria. The cellular material may contain chemical compounds which reversibly bond, for example, water molecules and which thus actively contribute to the fluid suction capacity.

The material can contain compounds which act as catalysts on the treatment effects.

The formed cavity system may be of random disposition or have a preferential major direction. This latter permits guiding the treatment fluid flow. Guiding can also be provided in the pore system by walls which are impermeable to the treatment fluid.

The cavity system may, in layers, have different diameters. Such layers may be structurally different from each other and be replaceable, or structurally merge in each other. One layer may consist of a continuous material and the superjacent of particles. Conceivably, the material may be denser in one region and looser in another with a gradual transition Commercially, materials of different cavity characteristics may be available.

For certain fields of use, the material needs to be pliable, soft and mouldable, for others a firmer possibly rigid structure is advantageous. The walls are made accordingly, soft to hard, possibly with an elastic component, or rigid. The material can, for example, be cut to suitable format according to certain basic material sizes. Such material can be shaped according to a part of the body. Possibly, the shell or layer 10 can be cupped with a possibility to apply particles between the part of the body and the shell. The porous material surface can be provided with adhesive regions for fixing against adjacent surface layers which are to be treated. As regards the material surface, this should, on its side facing the surface layer which is to be treated, have pores, spaces or capillary systems which establish contact between the surface layer and the cavity system.

The shell or layer 10 can cover larger or smaller parts of the cellular material 11. The shell 10 may be manufactured of, for example, plastics, glass, rubber or other rigid material or consist of a fluid-tight surface layer on the cellular material 11. The shell should have a surface tension distributing effect and influence the passage of liquid. The shell also contributes to directing the suction effect or pressure effect in the material and to retaining fluid in place in the material. The shell may have a greater surface area than the cellular material so as to make possible abutment against the skin. The shell 10 may possibly be fixed in the porous material at but one or several localized regions and can be a separate unit intended for application above a certain cellular material with one or more adhesion points. Furthermore, the shell may be provided with insulation to reduce heat losses into the ambient atmosphere. Suitably, the supply and removal conduits 12, 13 are then also insulated.

The cellular material 11 and shell 10 must, for application to humans, be pliable, soft as regards application on irregular ulcerations (see below). As regards application on regions where the skin is intact, a stiffer structure may be advantageous.

The device according to the invention has at least one fluid supply connection 12 and at least one fluid removal connection 13 which are located at a predetermined distance from each other. Factors of importance in determining the suitable mutual spacing are, int. al. the type of treatment fluid, capillary activity, cavity and wall characteristics and the applied pressure/suction. The connections 12, 13 can be designed in different ways. According to one alternative, each connection is formed of a ring of the shell material. The connections can also comprise holes in the shell 10, possibly distributed with suitable spacing, permitting the adaptation of material of standard size to treatment areas of different sizes. The connections 12, 13 can be placed in different parts of the cellular material with respect to the layer which is to be treated and can, furthermore, be movable by means of a simple retention device. The connections can, furthermore, be countersunk in the shell or cellular material and be coupled direct or via intermediate connecting pieces to extant conduits. The connections 12, 13 may have passages in their walls where they are in contact with the porous material. The connection conduits can also branch out in the cellular material and are suitably reinforced to prevent "throttling" or collapse under suction. The pressure or suction effect can be directed in the cellular material by means of one or more walls in the connection regions thereof. Each unit can have several fluid supply connections and fluid removal connections.

The supply and removal conduits can be coupled in an intermediate coupling piece for manual connection to a supply and removal assembly such that the patient himself can start the device and the treatment and discontinue this process e.g. in order to be able to get out of bed. This entails that the system places no great demands on personnel. Several material units, each one possibly with several connections for pressure/suction, can conceivably be interconnected so that supply of fluid at a certain pressure and/or discharge flow at a certain suction can be effected by means of one and the same manual or automatic control unit.

In the connection conduits, sensors can be provided for flow and temperature, and manometers with a possibility for manual or automatic registration and regulation.

Devices for preventing back flow may be provided, as well as filters. The supply flow is most simply effected by the intermediary of a drip bottle and discharge flow by means of vacuum suction. Automatic drip chambers or the possibility for automatically placing the supply flow under a certain pressure may be provided in accordance with known medical technology.

It is practical to apply a sensor 16 in the cellular material in order to sense the fluid saturation degree. This sensor may be based on the principle that the impedance between two electric conductors changes when the liquid

concentration between the conductors is altered. The terminal conductor 17 of the sensor 16 comprises wires, and a small regulator unit with a battery as alternative power supply permits registration and, after calibration, automatic regulation of the fluid saturation degree by coupling to the valve means of the regulator member 15. A temperature sensor may be disposed in the cellular material and be connected to the means of the regulator member 15 for cooling or heating the fluid.

The device according to the invention permits distribution and demarcation of treatment fluid within a determined area, regulatable treatment fluid flow and regulatable pressure/suction effect. Treatment effects are distributed through open pores vis-à-vis other fluid, other phases or solid material in accordance with the following operational example.

On use of the device for, for example, ulcer treatment, the free surface of the cellular material 11 facing away from the shell or layer 10 is applied to the tissue which, in Figs. 2—5, is designated 14, and the ulcer in the tissue.

Liquid which is supplied to the cellular material 11 will, because of the material structure, be distributed in and restricted to the material in accordance with laws of physics concerning surface tension and capillarity. In the material, conceivable states are from no wetting up to complete wetting as shown in Figs. 3—5. The wetting or saturation degree is related to the quantity of capillarily functioning pores. The state which is to be striven for is that which entails the same degree of wetting throughout the entire material.

If there are capillarily functioning, open pores in the cellular material 11 facing that skin area which is to be treated, the material will have a certain absorptive force distributed throughout the material surface. The absorptive force will be related to the degree of wetting in the material and to a possible partial vacuum if suction is exercised in the discharge connection 13. The fluid flow in the material is influenced int. al. by applied pressure or suction and by capillary forces. Caused by pressure/suction influence, the major direction of the fluid flow will be from the supply to the removal connection. Within the different parts of the cellular mterial, the flow direction will be determined by differences in the liquid saturation in adjacent material regions. The liquid will be moved in that direction where liquid saturation is lowest and where, consequently, capillary force is greatest. Substances which are sucked up in the material from adjacent tissue will pass towards regions where liquid saturation is lowest and, finally, towards the discharge suction. If the material is inert, the continuous treatment fluid flow will render the system self-purifying as regards contamination by molecules and particles in the size range up to pore/space or capillaries. The treatment fluid flow and sucking-up from the surface layer result in the removal of contaminants from the treatment surface. The sorption process which may be influenced by different liquid saturation degrees, and the described passage of substance with the fluid constitute, together with the chemical effects described below, considerable advantages in the invention.

Since a flow of treatment fluid is a precondition, chemical equilibrium will not be reached. Diffusion and concentration gradients control the exchange on the molecular level between treatment fluid and the tissue layer being treated. Differences in the osmotic pressure between treatment fluid and surface layer can be utilized for achieving a distribution effect. The inflow of liquid permits viscosity change in adjacent surface layers.

By regulating the fluid saturation degree in the material, it is possible to a certain extent to control the chemical effects. Regulation of fluid temperature and fluid flow rate permit tempering of the treated surface.

Two material layers, possibly with different treatment fluid characteristics according to the invention may permit added influence of each other independent of regulation possibilities.

Treatment fluid is adapted with regard to type, and, by means of additives, to the contemplated goal of treatment under consideration of the above-outlined, possible influences. It is conceivable to influence the liquid sucking of the system by using a capillary-active fluid or by the addition of suitable capillary-active substance.

A gas may be distributed in the cell material, its direction of flow being determined partly by applied pressure or suction, partly in accordance with possible preferential pore direction or controlled by possible fluid-impervious walls. Excess pressure in the material entails gas conveyance to the skin or the tissue and partial vacuum entails suction therefrom.

Operational Example

A. Application to ulcerations (skin damage with tissue loss)

Local treatment at the clinic is effected by means of ointment dressing, wet or dry, possibly tempered dressing, washing or removal by suction of secretions by means of special dressings. Substances of importance for healing are added, antibiotics, bactericides, enzymes for the degradation of dead tissue etc.

In itself, the invention constitutes a capillary system with certain similarities to the transport system which supplies the cells of the tissue with nutritive substances and removes degradation products. The invention provides the following treatment possibilities: supply of nutritive substances, oxygen, enzymes for the degradation of nectrotic material, the supply of antibiotics, the supply of liquid at optimum pH, the supply of medicaments with particular ulcer effects (zinc, vitamin A etc.). Osmotically active solutions can be supplied. Bacteriostatic or

bactericidic solutions may also come into question. The ulcer may quantitatively be hydrated by the assistance of the device according to the invention, and diffusion of treatment agent can, to a certain extent, be controlled. The ulcer wound can be tempered (heat/cooling). Collections of tissue liquid can be removed as a result of the continuous suction effect of the device. The system is self-purifying. As opposed to conventional dressing treatment, regular changes of dressing have proved to be unnecessary. The risk of infection in conjunction with dressing change is hereby reduced. Contaminant articles of a diameter which is greater than the pores of the material can be absorbed against the treatment side of the material and be removed when the material is taken off. In cases of particularly secretory ulcers, it has been possible to change the inner layer of pore material, for example, twice daily, while the outer layer with connections is retained for from one to two days.

Oxygen gas can be supplied, for example, in two layer systems in which the oxygen gas flow is introduced outside a liquid flow adjacent the ulcer. If the inner layer is moderately hydrated, the passage of gas is permitted to the base of the ulcer. Liquid contact prevents, at the same time, drying out. One advantage is that the porous material is inert and is not absorbed into the body. The risk of allergy is minimal.

Compared with conventional treatment, the device according to the invention is very simple to manage and requires fewer personnel. The patient himself can couple in the device. The environment in the ulcer can continuously or intermittently by supplied with different doses of treatment agent. The device can be used when the patient is ambulant. Medical care personnel then apply the cell material with suitable support dressing and an intermediate connecting piece accessible to the patient for connection to the flow conduits. Apart from this, it is required of the patient that he be capable of managing a drip bottle and manual suction assembly. The gains involved in such therapy may be seen in relation to the heavy care costs involved for in-patients.

B. Local treatment of burn injuries to skin

According to conventional local treatment of burn injuries, a dressing is applied, possibly with a liquid absorption capacity (Epigard®, Debrisan®). The surface is treated with bactericides or bacteriostatic substances or antibiotics. The body is tempered by initial cooling and, later in order to counteract excessive energy losses, heating.

The above wound treatments can all be carried out by means of the device according to the invention. Burn injuries caused by chemical agents can, according to the invention, rapidly be diluted with antidote, and injurious substances be sucked out of the skin.

C. Application to soft part injuries (inflammation) or fractures with unbroken skin

Local tempering of injured tissue is used as therapy.

According to the invention, a determined temperature effect can be imparted to an injured part of the body. At the same time, antiphlogistic substances can be added to the treatment fluid which, after skin passage (see D) further alleviates the reaction.

D. Application to eczema in various phases of inflammation or infection

Local treatment according to conventional methods as disclosed under A may be topical. Often however, use is made of occlusion treatment. This treatment comprises a hydrated dressing with a treatment agent and a sealing material overlaid on the outside. Hydration of intact skin increases the possibilities of diffusion of the treatment agent many times over. Passage out of the skin is also facilitated.

The device according to the invention, with adapted treatment fluid, permits continuous and regulated hydration of the skin with the above-disclosed increase of the diffusion possibilities for an added treatment agent — agent which can be replaced by further supply flow according as it is consumed. Liquid flow and suction effect also have a purifying influence in that the infective substance, inflammation mediators and degradation products are removed, and oedema is affected advantageously.

E. Cosmetic applications

1) According to conventional therapy, use is made, in the treatment of acne, of antibiotics and radiation with heat effect. The invention is employed with the application of a face mask, possibly with tempering and an addition of antibiotics or antiphlogistic substances to the treatment fluid.

2) Use in cosmetic indication so as to provide passage of liquid and molecular substances through the skin into and out of the tissue, for example in the cosmetic treatment of aging skin (face mask). Localized heating/cooling of the skin also provides a potential application in modifying the blood circulation through the skin for so-called vitalization purposes.

F. Other fields of application

Application against bacteria or cell growth substrate which makes possible a continuous, optimum supply of growth substances, replacement of substrate substances and removal of the degradation product. Tempering of the environment. Conventional technology does not allow for these effects.

Claims

1. A device for the treatment of a tissue area in an abnormal condition comprising a porous material (11) intended for abutment against the tissue and a fluid-impervious shell or layer which covers the material at least to an extent, said device having at least one connection for fluid supply and at least one connection for fluid removal, characterised in that the porous material consists of at least one layer of open-pore soft cellular material that can be readily conformed to said tissue area, that the fluid impervious shell only is disposed, at least to an extent, on one side of the cellular material and that the connections for fluid supply and removal are connected to the the shell in a spaced apart relationship in order to establish a treatment fluid flow coming into contact with the tissue area through the cellular material from the supply connection to the removal connection for influencing the tissue by sorptive processes, preferential passage of substances with the treatment fluid flow, by chemical processes and/or by tempering.

2. Device according to claim 1, characterised in that the fluid supply is arranged to take place under pressure and/or the fluid removal under suction.

3. Device according to claim 1 or 2, characterised in that electrodes (16) are disposed in the cellular material for sensing the fluid saturation degree and registering and/or regulating same by means of valves.

4. Device according to any one of the preceding claims, characterised in that temperature regulating means are disposed in the supply conduit.

5. Device according to any one of claims 1—3, characterised in that temperature sensing means are disposed in the cellular material (11).

6. Device according to any one of the preceding claims, characterised in that the cellular material (11) has fluid-impervious walls for guiding treatment fluid therein.

7. Device according to any one of the preceding claims, characterised in that the cellular material (11) has, on its side facing the tissue, a preferably replaceable micropore layer.

Revendications

1. Dispositif pour le traitement d'une zone de tissu en condition anormale, comportant un matériau poreau (11) prévu pour venir en appui contre le tissu et une enveloppe ou couche imperméable aux fluides couvrant le matériau, au moins dans une certaine étendue, ledit dispositif présentant au moins une connexion pour l'alimentation d'un fluide et au moins une connexion pour l'évacuation d'un fluide, caractérisé en ce que le matériau poreux est constitué d'au moins une couche d'un matériau cellulaire mou à pores ouvertes pouvant facilement prendre la forme de la dite zone de tissu; en ce que l'enveloppe imperméable aux fluides n'est disposée, au moins dans une certaine étendue, que d'un seul côté du matériau cellulaire; et en ce que les connexions pour l'alimentation d'un fluide et pour l'évacuation d'un fluide sont connectées à l'enveloppe à une certaine distance l'une de l'autre de façon à établir un flux de fluide de traitement venant au contact de la zone de tissu à travers le matériau cellulaire, en provenance de la connexion d'alimentation et en direction de la connexion d'évacuation, pour influencer le tissu au moyen de processus d'absorption, par passage préférentiel de substances avec flux de fluide de traitement, par processus chimiques et/ou par maintien au tiède.

2. Dispositif selon la revendication 1, caractérisé en ce que l'alimentation en fluide est prévue pour s'opérer sous pression et/ou l'évacuation du fluide sous dépression.

3. Dispositif selon la revendication 1 ou la revendication 2, caractérisé par des électrodes (16) dans le matériau cellulaire pour detecter le degré de saturation du fluide et enregistrer et/ou réguler ce même degré au moyen de robineterie.

4. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que des moyens de régulation de la température sont disposés dans la conduite d'alimentation.

5. Dispositif selon l'une quelconque des revendications 1—3, caractérisé en ce que des moyens de détection de la température sont disposés dans le matériau cellulaire (11).

6. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que le matériau cellulaire (11) présente des parois imperméables aux fluides pour y guider le fluide de traitement.

7. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que le matériau cellulaire (11) comporte, du côté qui fait face au tissu, une couche microporeuse, de préférence remplaçable.

Patentansprüche

1. Vorrichtung zum Behandeln einer sich in einem anormalen Zustand befindenden Gewebefläche, umfassend ein zur Anlage gegen das Gewebe bestimmtes, poröses Material (11) und eine das Material zumindest teilweise deckende, flüssigkeitsundurchlässige Schale oder Schicht, sowie zumindest einen Anschluss zur Flüssigkeitszufuhr und zumindest einen Anschluss zur Flüssigkeitsabfuhr, dadurch gekennzeichnet, dass das poröse Material aus zumindest einer Schicht eines weichen, der genannten Gewebefläche leicht anpassbaren Zellenmaterials mit offenen Poren besteht, dass die flüssigkeitsundurchlässige Schale zumindest teilweise nur auf einer Seite des Zellenmaterials angebracht ist, und dass die zur Flüssigkeitszufuhr und -abfuhr dienenden

Anschlüsse im Abstand voneinander mit der Schale verbunden sind, um eine mit der Gewebefläche in Berührung gelangende Strömung von Behandlungsflüssigkeit durch das Zellenmaterial vom Zufuhranschluss zum Abfuhranschluss zwecks Einwirkung auf das Gewebe durch sorptive Prozesse, vorsugsweise den Durchgang von Stoffen mit der Behandlungsflüssigkeits-Strömung, durch chemische Prozesse und/oder durch Temperieren zu etablieren.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Flüssigkeitszufuhr unter Druck und/oder die Flüssigkeitsabfuhr unter Saugwirkung erfolgt.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass im Zellenmaterial Elektroden (16) angebracht sind, um den Flüssigkeitssättigungsgrad abzufühlen und zu registrieren und/oder mit Hilfe von Ventilen einzuregeln.

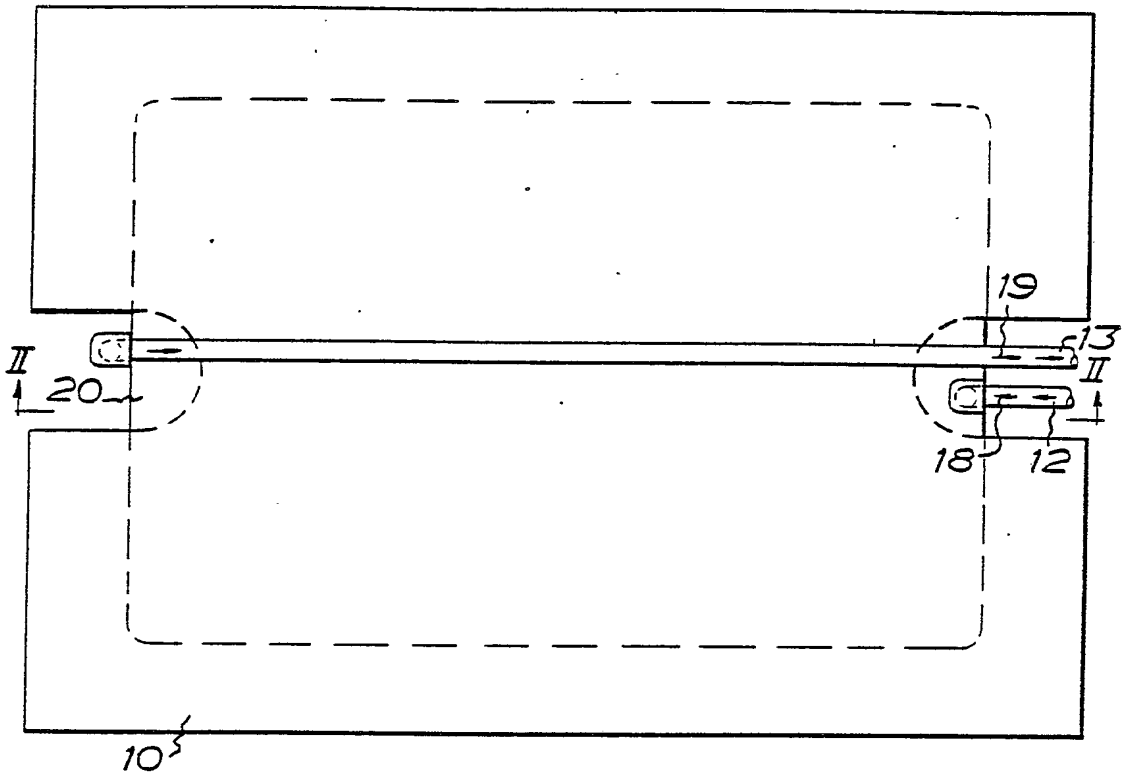
4. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass in der Zufuhrleitung Temperatureinregelungsmittel vorgesehen sind.

5. Vorrichtung nach einem der Ansprüche 1—3, dadurch gekennzeichnet, dass im Zellenmaterial (11) Temperatureinregelungsmittel vorgesehen sind.

6. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass das Zellenmaterial (11) flüssigkeitsundurchlässige Wände aufweist, um Behandlungsflüssigkeit darin zu leiten.

7. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass das Zellenmaterial (11) auf seiner dem Gewebe zugewandten Seite eine vorzugsweise auswechselbare, mikroporöse Schicht aufweist.

FIG. 1



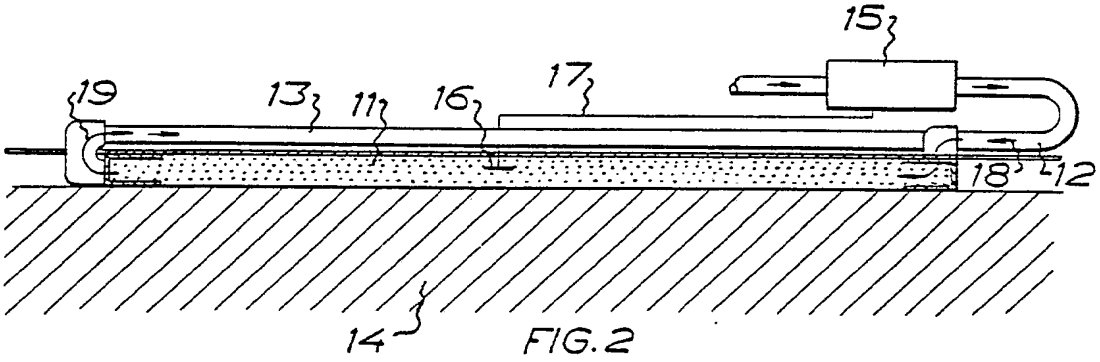


FIG. 2

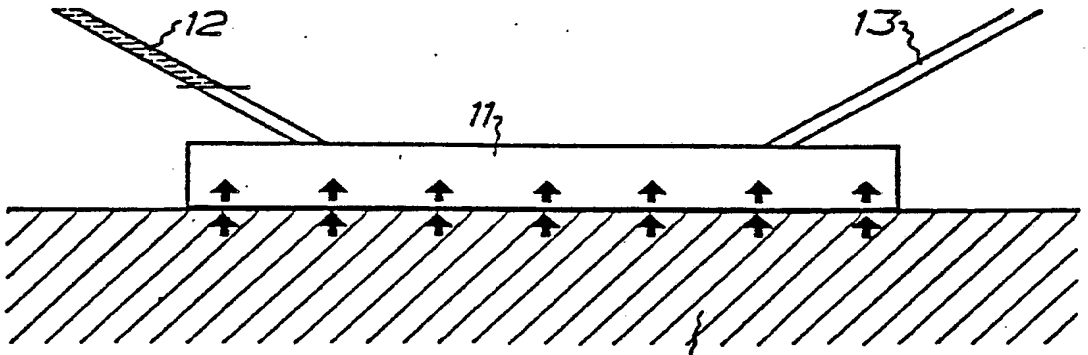


FIG.3

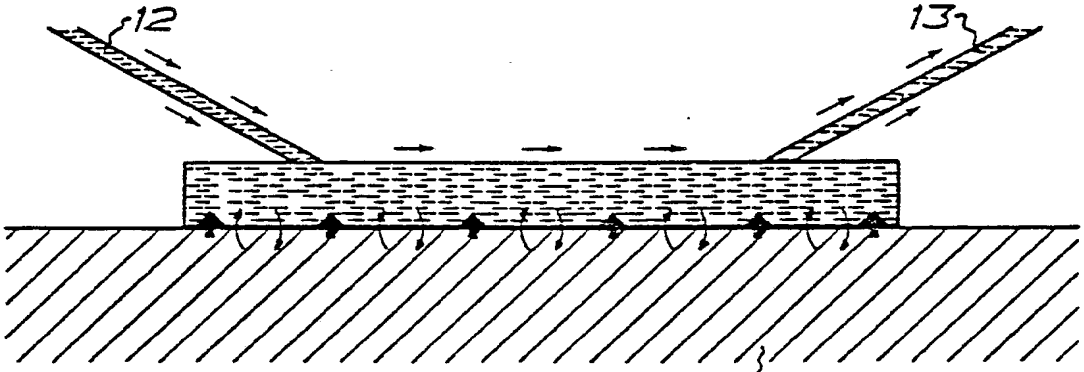


FIG.4

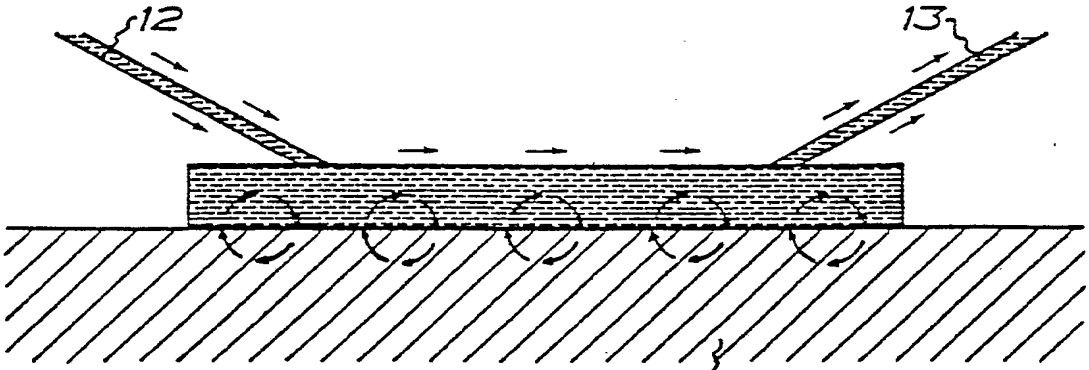


FIG.5